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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,989	05/29/2001	Wilfred Wayne Lautt	2495.00071	7861

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,989	LAUTT, WILFRED WAYNE	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to Applicant's amendment received Dec. 17, 2003.

Claims 5-8 and 14-18 are cancelled. No new claims are added.

Claims 1-4 and 9-13 are currently pending.

The finality of the office action mailed Sep. 17, 2003 is withdrawn and prosecution on the merits is reopened in view of the following new ground(s) of rejection.

New Ground(s) of Rejection

Claim Objection(s)

1. Claims 1-4, 11, 13 are objected to because of the following informalities: in claim 1, line 2, after "patient", the phrase –in need thereof—should be added. In claims 2-4, 11 and 13, line 2, "further" should be deleted. Appropriate correction is required.

Claim Rejection(s)—35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for intra-portal administration of an NO donor or agonist compound, does not reasonably provide enablement for (1) any other type of administration of an NO donor or agonist and (2) all types of compounds which fall within the scope of "nitric oxide donors or agonists". The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among the factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claimed; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention

The claims are drawn to a method for increasing insulin sensitivity in a mammalian patient by administering to the patient an effective amount of a nitric oxide donor or agonist.

(2) The state of the prior art

The art recognizes that insulin resistance is seen in a variety of medical conditions such as non-insulin dependent diabetes, obesity, etc. and that reversing this resistance is one therapeutic approach to effective treatment.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are very broad and are drawn to the administration of any compound capable of being a NO donor or agonist. Additionally, the claims also encompass various modes of administration.

(6) The amount of direction or guidance presented

Applicant's specification does not provide guidance for the method as claimed. Initially, Applicant admits that only intra-portal administration of the NO donor or agonist actually reverses insulin resistance thereby increasing insulin sensitivity (please see the specification, page 30, lines 10-16). Thus the claims are only partially enabled for intra-portal administration of a NO donor or agonist.

Next, the claims embrace the administration of any compound, e.g. peptide, nucleotide, non-peptide organic compound, etc, capable of having NO donor or agonist activity. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled in cases involving chemicals and chemical compounds, which differ radically in their properties, it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combination included in the claims are capable of accomplishing the desired result." In this case, Applicant's specification does not set forth a representative number of examples of the claimed NO oxide donor and agonist compounds, which would actually be capable of increasing insulin sensitivity.

(7) The presence or absence of working examples

The specification describes various examples using pentobarbital-diabetic rat models, wherein the efficacy of only one compound, SIN-1, in reversing insulin resistance is assessed. Moreover, the examples test the efficacy of this compound when administered intravenously or intra-portally. Applicant discloses that intravenous administration did not reverse insulin resistance whereas intra-portal administration was effective at reversing insulin resistance. Please refer again to page 30, lines 10-16.

(8) The quantity of experimentation necessary

Since, (1) the claims are very broad and encompass the administration of any compound having NO donor or agonist activity; (2) the specification does not provide a representative number of compounds capable of increasing insulin sensitivity such that the scope of enablement is reasonably correlated to the scope of protection sought by the claims; (3) compound structure and activity for pharmaceutical use must be determined from case to case by painstaking experimental study; and (4) since, through applicant's admission, the claims are only partially enabled for intra-portal administration, one of ordinary skill in the art would be burdened with undue experimentation to determine which compounds and which mode of administration would be capable of increasing insulin sensitivity in a mammalian patient in need thereof.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations "nitric oxide donor" and "nitric oxide agonist" render the claims vague and indefinite. The specification does not clearly set forth explicitly and with reasonable clarity the definition of this limitation. Instead, what is described at page 8, lines 10-15 is merely exemplary and does not describe what would be excluded by the limitations. Therefore, the metes and bounds of the patent protection desired are unclear, and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed method.

Claim Rejection(s)—35 USC 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cameron et al. (submitted by Applicant in IDS of Jan. 31, 2002)

Cameron et al. disclose a method of treating streptozocin-diabetic rats with effective amounts of the nitric oxide donor, isosorbide dinitrate administered orally. The method assesses the effect of the nitric oxide donor on nerve conduction velocity in the rats. Please see the abstract; page 19, second column, lines 1-5 under *Nerve conduction velocity studies*; page 23, first column, first full paragraph.

Cameron et al. anticipate the claims because Cameron et al. disclose administration of an identical active agent, i.e. nitric oxide donor, to a mammalian host using Applicant's claimed method steps. Therefore, absent evidence to the contrary, an

increase in insulin sensitivity would be an inherent characteristic of the treatment. Furthermore, please note that the diabetic rat model taught by Cameron et al. is predictive of a mammalian diabetic patient.

Conclusion

Claims 1-4 and 9-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
September 16, 2004

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER